arplay medical

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SEP 2 1 2001

**Premarket Notification [510(k)] Summary**
**Tab 4**

K004023
p. 1 of 2

December 15, 2000

Trade Name: Intra Operative Radiation Therapy System

Common Name: Accessory for Intra Operative Radiation Therapy

Classification Name: Medical Linear Accelerator Accessory, 90 LHN (per 21 CFR section 892.5050)

Manufacturer's Name: Arplay Medical S.A.
Address: 1 Route de Citeaux
21110 Izeure
France

Corresponding Official: Richard Borgi, MD
Title: President and CEO
Telephone: +33-3-8029 7401
Fax: +33-3-8029 7622

Predicate: General Electric Co., Intraoperative Radiation Therapy Device, K891261

Device Description: The Intra Operative Radiation Therapy System consists of a selection of treatment cone localizers, a selection of collimators, and a telescopic device that connects the cones to the linear accelerator and to aligns the electron radiation beam to the center of the cone. These components are listed below.

Components of the Intra Operative Radiation Therapy System

1. Telescopic Device: Level 2 collimation & linac connection
2. 2 Perspex straight end cones (localizers): 90 mm & 110 mm
3. 2 Perspex 30 degree beveled cones: 90 mm & 110 mm
4. 2 Perspex straight end cone with chromed brass end: 90 mm & 110 mm
5. 2 Perspex 30 degree beveled cone with chromed brass end: 90 mm & 110 mm
6. 7 Lead collimators, level 2
7. 6 brass collimators, level 3
8. Level 3 collimator handling tool
9. Perspex cone cover
10. 4 Optional scattering foils
11. Optional optical viewer

The surgeon and radiation oncologist, using their clinical knowledge, select the appropriate sterilized treatment cone and place it in the patient during

surgery while in the operation room. The Telescopic Device is attached to the treatment head of the linear accelerator. The cone is attached to the telescopic device and the safety key switch is activated to prevent motion of the gantry or collimator after docking. After treatment the steps are reversed and the patient is returned to the operating room for removal of the cone and closure of the surgical site.

Intended Use: The Intra Operative Radiation Therapy System is to be used in conjunction with a linear accelerator for electron beam radiation therapy during a surgical procedure.

Technological Characteristics: See the attached Predicate Comparison Table

| # | Feature | General Electric Co., Intraoperative Radiation Therapy Device, K891261 | Arplay Medical Intra Operative Radiation Therapy System |
|---|---|---|---|
| 1 | Telescopic Docking Device | Yes, Attaches to Linac | Yes, Attaches to Linac |
| 2 | Perspex Treatment Cones | 90 mm O.D.: Straight & Bevel ends<br>110 mm O.D.: Straight & Bevel ends | 90 mm O.D.: Straight & Bevel ends<br>110 mm O.D.: Straight & Bevel ends |
| 3 | Perspex Treatment Cones with chromed brass end | 90 mm O.D.: Straight & Bevel ends<br>110 mm O.D.: Straight & Bevel ends | 90 mm O.D.: Straight & Bevel ends<br>110 mm O.D.: Straight & Bevel ends |
| 4 | Level 3 Brass Collimator rings | 40, 50, 60, 70, 80,& 90 mm | 40, 50, 60, 70, 80,& 90 mm |
| 5 | Optional Level 2 Lead Collimators | 38,48,58,68,78, 88,& 98mm | 38,48,58,68,78, 88,& 98mm |
| 6 | Optional Level 2 Scattering Foils | 4 | 4 |
| 7 | Optional lighted viewing scope | Yes | Yes |
| 8 | Key controlled Safety System | Yes | Yes |
| | | | |

The Arplay Medical Intra Operative Radiation Therapy System has the same intended use and safety characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2001

Richard Borgi, M.D.
President & CEO
Arplay Medical S.A.
1 Route de Citeaux
21110 Izeure France

Re: K004023
Trade/Device Name: Intra Operative Radiation Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: July 12, 2001
Received: July 20, 2001

Dear Dr. Borgi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Tab 3

## Indications For Use

510(k) Number: K004023

Device Name: : Intra Operative Radiation Therapy System

**Indications for Use**:
Accessory system to be used in conjunction with a linear accelerator for electron beam radiation therapy during a surgical procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K004023

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)